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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,705	08/02/2001	Richard M. Amasino	960296.97214	6991

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,705	AMASINO ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2003 and 29 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,24 and 26* is/are rejected.

7)☒ Claim(s) *23, 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/6/02, 8/2/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-27 are pending.

2. The claims were renumbered as per Rule 1.126. The original claims 1-26, are renumbered 1-27. The original claims 1-24 of Group I are renumber 1-25, and original claims 25-26 of Group II are renumbered 26-27.

3. Applicant's election with traverse of Group I, claims 1-24 (original) to the extent that they are drawn to SEQ ID NO:2 in sense orientation in the reply filed on 5/29/2003 and 6/29/2004 is acknowledged.

The traversal is on the ground(s) that both groups are classified in class 800, subclass 290. Thus there is no additional burden on the office to consider all these claims in a single examination (paragraph bridging pages 1-2 of 5/29/2003 response).

This is not found persuasive because distinct inventions can be classified in the same class and subclass and while the search of the prior art for one group may overlap with that of another, they are not co-extensive of each other and thus would be a burden on the Office. Upon further consideration, original claim 25, which is renumbered as claim 26, will be examined along with the claims of Group I, because it is drawn to subject matter of Group I.

Applicants also contend that they are entitled to claims that would encompass any nucleotide sequences which would express the protein of SEQ ID NO:3 (page 2, 2nd paragraph of 5/29/2003 response).

No claims are drawn to nucleic acids encoding SEQ ID NO:3.

The requirement is still deemed proper and is therefore made FINAL.

Claim 27 is withdrawn from consideration for being drawn to a non-elected invention.

4. Claims 1-26 to the extent that they are drawn to SEQ ID NO:2 in sense orientation, are examined in the present office action.

Specification/Priority

5. If applicant desires benefit of a previously filed provisional application under 35 U.S.C. 119(e), specific reference to the earlier filed application must be made in the instant application. 37 CFR 1.78(a)(5)(i) requires that any nonprovisional application, or international application designating the United States, claiming the benefit of one or more prior-filed provisional applications must contain, or be amended to contain, a reference to each such prior-filed provisional application identifying it by provisional application number. Amending the first sentence of the specification to recite "This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application 60/222,550, filed 8/3/2000" will obviate the objection.

Specification

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See for example page 18, paragraph 69. See MPEP § 608.01.

Objection is made to the specification for not incorporating SEQ ID NO's when referring to nucleic acid or amino acid sequences. 37 CFR 1.821(d) requires the use of the assigned sequence identifier (e.g. SEQ I.D. NO: X) in all instances where the description or claims of a

patent application discuss sequences. See for example page 19, paragraph 74, and page 21, paragraph 77.

Claim Objections

7. Claims 1, 5, 8, 13, 16, 20, 23 and 25 are objected to for being drawn to non-elected inventions. Correction is requested.

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 25 is dependent on claim 23. Because the claims were renumbered, the Office believes that claim 25 should be dependent on claim 24. For purposes of compact prosecution, claim 25 will be examined to the extent that it is dependent on claim 24. Correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-4, 6-12, 14-19, 21-22, 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 8-9, 12, 16, 19, 22, 24 and 26 are indefinite in the recitation "FPA". The sole designation of a DNA or amino acid sequence by "FPA" is arbitrary and creates ambiguity in the claims. For example, the DNA or amino acid sequence in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different DNA or amino acid sequence. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F .2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would obviate this rejection.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4, 6-12, 14-19, 21-22, 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a transgenic plant comprising a FPA polynucleotide in sense orientation, or comprising a genetic construct comprising said polynucleotide, or wherein the FPA polynucleotide is from Arabidopsis, or seed from said transgenic plant or plant from said seed; or a plant seed comprising a genetic construct comprising a FPA polynucleotide in sense

orientation, or wherein the FPA polynucleotide is from Arabidopsis, or a transgenic plant from said seed; an isolated DNA sequence comprising the coding sequence for the FPA gene from Arabidopsis or an isolated DNA sequence comprising a DNA sequence encoding the FPA protein from Arabidopsis; or method of producing a transgenic plant with altered flowering comprising an FPA polynucleotide sequence.

Applicants isolated the FPA gene by positional cloning performed on fpa mutants of the Columbia ecotype of Arabidopsis. Applicants were able to complement the fpa mutants using clones comprising genomic DNA from BAC 1024. The rescued clones all contained the same region of DNA (page 18, paragraphs 68-71). Applicants disclose a sequence for the entire FPA gene from Arabidopsis is set forth in SEQ ID NO:1. The cDNA protein coding sequence for the FPA gene is set forth in SEQ ID NO:2 and its deduced amino acid sequence is set forth in SEQ ID NO:3 (page 7, paragraph 27).

The Applicants do not identify essential regions of the FPA polynucleotide of SEQ ID NO:2 or FPA protein encoded by SEQ ID NO:2, nor do Applicants describe a genus of FPA polynucleotide sequences that encode a FPA protein with the same function as the FPA protein encoded by SEQ ID NO:2.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of

what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences from a representative number of plants encoding a FPA protein falling within the scope of the claimed genus of polynucleotides. Applicants only describe a single genomic and cDNA sequence of SEQ ID NO:1 and 2, respectively. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the FPA polynucleotide or protein, it remains unclear what features identify an Arabidopsis FPA polynucleotide or protein. Since the genus of FPA polynucleotides or proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

10. Claims 1-22, 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1 and 2 encoding SEQ ID NO:3 and Arabidopsis transformation therewith, and a method for increasing the time to flowering in Arabidopsis comprising transforming Arabidopsis with a construct comprising SEQ ID NO:1 or

2 operably linked to a promoter in sense orientation, wherein SEQ ID NO:1 or 2 encodes the polypeptide of SEQ ID NO:3, does not reasonably provide enablement for any isolated DNA sequence comprising the coding sequence for the FPA gene from Arabidopsis or wherein said sequence encodes any FPA protein from Arabidopsis, any plant or seed transformed with any FPA polynucleotide sequence wherein the plant exhibits an altered flowering time, or method of producing a transgenic plant with altered flowering characteristics comprising introducing a FPA polynucleotide sequence into any plant, or wherein the altered flowering characteristic is delayed flowering. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a transgenic plant or plant seed comprising a FPA polynucleotide in sense orientation which causes the plant to have an altered flowering time as compared to non-transgenic plants of the same species, or comprising a genetic construct comprising said polynucleotide, or wherein the FPA polynucleotide is from Arabidopsis, or

wherein the FPA polynucleotide has the sequence set forth in SEQ ID NO:2, or seed from said transgenic plant or plant from said seed; an isolated DNA sequence comprising the coding sequence for the FPA gene from Arabidopsis or an isolated DNA sequence comprising a DNA sequence encoding the FPA protein from Arabidopsis; or method of producing a transgenic plant with altered flowering comprising an FPA polynucleotide sequence.

Applicants isolated the FPA gene by positional cloning performed on *fpa* mutants of the Columbia ecotype of Arabidopsis. Applicants were able to complement the *fpa* mutants using clones comprising genomic DNA from BAC 1024. The rescued clones all contained the same region of DNA (page 18, paragraphs 68-71). Applicants disclose the sequence for the entire FPA gene from Arabidopsis is set forth in SEQ ID NO:1. The cDNA protein coding sequence for the FPA gene is set forth in SEQ ID NO:2 and its deduced amino acid sequence is set forth in SEQ ID NO:3 (page 7, paragraph 27). Applicants disclose Arabidopsis plants transformed with a construct comprising the entire FPA gene from Arabidopsis exhibited early flowering compared to Arabidopsis plants not transformed with said construct (pages 19-20, paragraphs 74 and 75).

Applicants broadly define "FPA polynucleotide sequence" as a genomic or cDNA sequence that is modified to contain minor nucleotide additions, deletions, or substitution or a synthetic DNA sequence (page 8, paragraph 29). This definition reads on sequences that are greatly variant from SEQ ID NO:2.

The state-of-the-art teaches transforming plants with heterologous genes that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1

is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant's broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a "range of phenotypes which include abnormalities in leaf and petal shape as well as stem height and number" (page 365, right column, 1st paragraph).

Applicants' claims are broadly drawn, reading on any nucleic acid sequence, as discussed above. The state-of-the-art teaches that not all nucleic acid sequences affect flowering when transformed into a plant. Roberts et al (August, 2000, U.S. Patent Number 6,096,946) teach a nucleic acid sequence encoding a polygalacturonase that when expressed in a plant, controls dehiscence in a plant in need thereof (columns 21-24, claims 1-43) and does not affect flowering, absent evidence to the contrary.

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:2 as probes or by designing primers to undisclosed regions of SEQ ID NO:2 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce plants that exhibit an early flowering phenotype.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 6-7 and 14-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 6-7 and 14-15 are drawn to a seed of the transformed plant and a plant grown from said seed. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny (seeds), it is unclear whether the claimed seeds, would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy , Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the seeds or plants comprise the construct that was introduced into the parent plant would overcome the rejection.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4, 6-12, 14-19, 21-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Perez et al (June, 2000, WO 00/32780, listed in IDS).

The claims are drawn to a transgenic plant or seed comprising a FPA polynucleotide sequence operably linked to a promoter in sense orientation which causes the plant or a plant from said seed to have an altered flowering time compared to a non-transgenic plant, or wherein the plant flowers earlier compared to a non-transgenic plant, or wherein the plant flowers later compared to a non-transgenic plant, or wherein the FPA polynucleotide is from Arabidopsis.

Applicants broadly define "FPA polynucleotide sequence" as a genomic or cDNA sequence that is modified to contain minor nucleotide additions, deletions, or substitution or a synthetic DNA sequence (page 8, paragraph 29). This definition reads on sequences that are greatly variant from SEQ ID NO:2. Applicants define "FPA gene" as SEQ ID NO:1 and the analogous gene sequences from other plants, and the variations and mutants thereof which retain flowering functionality (page 7, paragraph 28).

Perez et al disclose a plant transformed with a nucleic acid sequence from Arabidopsis, that alters the flowering time of the transformed plant, wherein flowering is early or late (page 30, lines 3-13; pages 62-63, claims 1-15). Perez et al also disclose seeds of transformed plants, and plants from said seeds (pages 28 line 15 to page 29, line 12). The transformed plants of Perez et al are encompassed by Applicants' claims given Applicants' broad definition of "FPA polynucleotide sequence" as discussed above, and because the Office interprets the nucleic acid

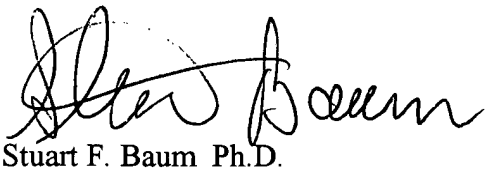
of Perez et al to be a variation or mutant of the FPA gene, given Applicants' definition of "FPA gene" as discussed above, and as such, Perez et al anticipate the claimed invention.

13. Claims 23 and 25 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide encoding SEQ ID NO:2.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
May 16, 2005